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Information of this handbook is, to our knowledge, exact.

Because of continuous research and development, the specifications of this product can be modified at any moment without notice.

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## ABOUT THIS HANDBOOK

#### AIM OF THIS HANDBOOK

This manual is part of the accompanying documents and thus an integral part of the device. It contains the full technical specifications of the *MacoTronic B2* equipment and necessary information to support the operator. Before operating, the user must have been trained by *MacoPharma* on how to use the device to achieve optimal results.

The device may only be operated by persons who have been trained on proper operation and handling. The manual must also be studied carefully before attempting to operate the device.

The information in this document is subject to change without prior notice in order to improve reliability, design and function and does not represent a commitment on the part of the manufacturer.

Assembly, extensions, adjustments, modifications or repairs may only be carried out by *MacoPharma* or authorized personal.

MacoPharma produces this handbook with an aim of providing simple and precise information. MacoPharma cannot of this fact ensuring any responsibility for all or bad interpretation. Although all the efforts were made to propose a handbook as exact as possible, this last can however comprise technical inaccuracies and/or typographical errors.

The owner of the material is held to preserve this handbook throughout all the apparatus lifespan with obligation to transmit it to the purchaser in the event of resale.

The recommendations relating to the declaration of conformity of the European Community, to the guarantee and the field of application are also included in this handbook.

Any information or modification relative to this handbook will have to be addressed to: MacoPharma

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#### STRUCTURE OF THE HANDBOOK

For an easy consultation, the handbook adopts the following structure:

- General presentation of the equipment.
- Setting-up.
- Use.
- Software configuration.
- Error and warning messages.
- First step maintenance.
- Technical data.

#### WHO IS THE READER

This handbook is addressed to any professional wishing to use the present equipment.

## HOW TO USE THIS HANDBOOK

We recommend to read this handbook attentively and to apply the mentioned restrictions.

#### THE CD ROM

The CD Rom contains this handbook in an electronic format (*pdf*).

The reading or the impression of this handbook presented in a *pdf* format requires the presence on the computer of a specific reading software named *Acrobat Reader* and available in free remote loading on the *www.adobe.com* site.

#### MENTIONED TRADE MARKS

Microsoft and Windows are registered trademarks of Microsoft Corporation in the United States and in other countries.

Adobe and Adobe Acrobat Reader are marks of Adobe Systems Incorporated.

## DELIVERED EQUIPMENT

The equipment is delivered with a specific pallet together with the following parts:

Item	Description
1.	MacoTronic B2 equipment.
2.	4 Holders.
3.	Compliance certificate.
4.	Power cord.
5.	Hand scanner
6.	Report printer.
7.	Label printer.
8.	MacoTrace CD Rom.
9.	User manual in english

## SAFETY

#### **GENERAL DATA RELATING TO SAFETY**

This *MacoTronic B2* equipment complies with the Medical Device Directive 93/42/EEC and fulfills the requirements of standards for Electrical safety EN 61010-1:2010 and for Electromagnetic Compatibility EN 61326-1:2006. Manufactured and tested in accordance with those standards, the equipment leaves the factory in perfect technical safety conditions. In order to preserve these conditions and to guarantee a safe use of the equipment, the user must conform to the indications and the symbols contained in this handbook.

Before the installation, check that the mains voltage and the apparatus selected voltage coincide.

When the full safe use is not possible any more, the *MacoTronic B2* equipment must be put out of service and preserved against an accidental use.

The use in full safety is not guaranteed any more in the following cases:

- The MacoTronic B2 equipment is obviously damaged.
- The MacoTronic B2 equipment does not work anymore.
- After a long storage under unfavorable storage conditions.
- After serious damage undergone during transport.

#### INSTRUCTIONS RELATING TO SYMBOLS AND SAFETY

This paragraph details the safety symbols as well as the elementary recommendations intended to ensure the safety of the users and the maintenance technician.



Any person using or intervening on the equipment will have to apply these safety advices. The operator in charge of maintenance must have competences and the necessary information to understand the operation of an electronic device. All the users will observe the rules and the security policies of their company.

#### Symbols used on the equipment

#### Electrical symbol

Electric safety labels are affixed on the outside and the interior of the instrument. If one of the labels is absent, it will be immediately and imperatively replaced by a new identical one.



This symbol means:

Power supply: to take care of risks of electrocution.

Triangles with yellow bottom showing the symbols of electric danger are affixed on the elements presenting a risk of electrocution.



This symbol means:

Ground of protection: frame of the *MacoTronic B2* equipment to be connected to the ground.

#### Symbol of nonspecific risk



This symbol means:

Non specific risk. These warnings draw the attention of the user to the precautions to be taken for the effective and safe use of the *MacoTronic B2* equipment. For example, this sign indicates the possibility of an eye exposure to a strong intensity light or the possibility of wedging the fingers (illumination drawer).

#### Symbols used in the handbook



This symbol means:

Information is underlined within the use of the equipment. No danger is incurred by the user if this point is not followed.



This symbol means:

High temperature. Risk of scorch is incurred by the user if this point is not followed.

#### **OPERATOR SAFETY**

Any action carried out using the *MacoTronic B2* equipment is submitted to safety advices. Each operator must comply with the rules of his laboratory. Any action taken is done under the operator's responsibility and his laboratory.

#### General safety

The MacoTronic B2 equipment must be installed in an aerated zone with a controlled room temperature ( $20^{\circ}C \pm 2^{\circ}C$ ).

Like any device, this equipment can have an electrical, electronic or mechanical breakdown. The manufacturer cannot be responsible of the treated products whatever they are, which would be lost following this breakdown and this, even during the period of guarantee.

The *MacoTronic B2* equipment describes in this handbook is intended to be exclusively used by a personnel beforehand trained. The operations of maintenance must be exclusively realized by qualified and authorized personnel. For a correct and sure use as well as for all interventions of maintenance, it is essential that the personnel observe the normal safety procedures.

Any use of the equipment contrary to that laid out in the instructions for use documentation may affect the quality of treated products and the safety of users.

Any use of accessories not supplied by the manufacturer may affect the quality of treated products.

Do not use the Macotronic B2 under dangerous atmospheric conditions or with dangerous materials which have not been designated for use with the Macotronic B2.

In order to avoid risk of electrocution, do not expose the unit to rain or excess moisture. The machine should be used inside a building.

Disconnect power before general servicing. Never power on with covering parts dismounted.

The button "|" is used to turn on the machine. The shutdown is carried out using a soft button displayed on the screen, which will trigger the termination of the program and the extinction of the instrument within 2 minutes. Never unplug by pulling out the wire.

Unplug the machine at the wall socket if the equipment is not to be used for a prolonged period. Unplug only at the adapter point, never by pulling on the cord. The space behind the machine should be at least 20 cm to allow an easy unplug of the power supply cable.

Do not dismantle the machine or attempt repairs. Maintenance is strictly reserved for qualified personnel

Periodically (daily or at least once per week minimum) or after each incident, the operator must clean the *MacoTronic B2* equipment (see Current maintenance procedure).

#### **Battery**



Product contains 2 battery buttons (type CR2032).

Risk of explosion is given by an incorrect type.

Contact a qualified technician to replace it.

DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.

#### Safety related to the manipulation of blood component

The users must carry protective gears adapted for operators working in laboratory (safety glasses, lab coat, rubber gloves, etc).

#### PRECAUTIONS IN THE EVENT OF A BREAKDOWN

When one suspect that the *MacoTronic B2* equipment is not sure any more (for example because of damage undergone during transport or during its use), it must be put out of service. It is necessary to make sure that it will not be used accidentally. The *MacoTronic B2* equipment will be repaired by authorized technicians.

# PROTECTION OF PLASMA FROM LIGHT DURING AND AFTER THERAFLEX MB-PLASMA TREATMENT

The Instructions for use for the THERAFLEX MB-Plasma systems have recently been changed. Among other minor changes the following sentences were added:

- Do not expose to light the treatment bag containing plasma and methylene blue before illumination.
- After sampling, protect the sample from the light up to the control.

This document describes in more detail the underlying rationale.

Some customers have recognized during their routine quality control that there was a variation in the fibrinogen recovery in different production facilities. One of the reasons identified was a different workflow between the different centres.

The treatment with the THERAFLEX MB-Plasma system includes the illumination with visible light. This illumination process reduces the amount of some plasma factors, e.g. functional fibrinogen. Such an effect could also occur when the illumination bags with dissolved methylene blue are exposed to day light or artificial light. This influence was investigated and it was shown that illumination with strong light doses (sunlight; 25.000 Lux) for 60 min before and/or after treatment could reduce functional fibrinogen by 10-14 %. Moderate light doses (10.000 Lux) have only a minor detrimental effect. Detailed results are shown in table 1.

Table 1: Reduction in functional fibrinogen under different storage conditions

	Condition E 0 / MACOTRONIC / 25.000 Lux		Condition F 0 / MACOTRONIC / 10.000 Lux	
	Mean %	SD	Mean %	SD
After 1h ## 000 Lux (bag)	10,29%	5,18%	5,88%	2,17%
	Condition G		Condition H	
	10.000 Lux / MACOTRONIC / 10.000 Lux		25.000 Lux / MACOTRONIC / 25.000 Lux	
	Mean %	SD	Mean %	SD
After 1h ## 000 Lux (bag)	3,72%	1,65%	13,81%	3,21%

The workflow of the THERAFLEX MB-Plasma procedure is dependent on the local setting of the blood bank. This could lead to MB plasma-containing illumination bags which are stored for a certain period of time before or after illumination, because e.g. the Macotronic is running.

Consequently, and in order to allow a more consistent procedure, the IFU of the respective bag systems was made more precise by introducing the above mentioned sentences, so that a possible influence of light would be minimized.

The protection of the MB-plasma containing bag from light before Macotronic illumination and before Blueflex filtration can be done by one of the following measures:

- Putting the bags into a box
- Placing the bags into a drawer
- Storing the bags in a dark room

A protection during the filtration steps is not necessary.

These instructions should also be considered for the numbered tubing segments of MB-treated plasma (used for quality control) that should also be kept away from light. (13% to 25% loss if exposed to light doses for 60 min).

In all cases the validation or quality control data and acceptance criteria of the respective blood bank under their routine production conditions are pivotal.

Dr. Stefan Reichenberg

Sym Kul- leer

(Scientific Marketing Manager Transfusion)

#### **CE MARKING**



The equipment has a CE MDD 93/42/EEC marking located on the rear part of the *MacoTronic B2* equipment.

#### DESTRUCTION OF THE EQUIPMENT



In accordance with directive (2002/96/CE), this device can be made up by harmful electronics components for the environment. It is requested to the owner to get into contact with the producer or distributor, in order to take note of the procedure to be followed for the recycling of the *MacoTronic B2* equipment. The producer cannot be responsible for the recycling of a *MacoTronic B2* equipment which will not have followed the definite procedure.



The equipment contains a button type battery for the real time clock. This battery will be removed prior to the destruction of the MacoTronic B2 and deposited in a collection center for used batteries.

#### **DECLARATION OF CONFORMITY TO THE STANDARDS**

The medical device for inactivation of pathogens in plasma by photo-treatment with methylene blue (THERAFLEX MB-Plasma procedure) conforms to the European Directive 93/42/EEC.

The MacoTronic B2 illumination equipment conforms to the following norms.

#### Electrical safety

EN 61010-1:2010 and EN 61010-2-081:2001 (Security rules for electrical apparatus for measuring, regulation and the laboratory.)

#### **EMC**

EN 61326-1:2006 (Measuring, Control and Laboratory Electrical systems). Class A equipment.

# GUARANTEE, LIMIT OF RESPONSIBILITIES AND PROPERTY RIGHTS

#### **GUARANTEE**

The guarantee of the equipment only applies if the equipment is installed in accordance with the present handbook and is used in accordance with the delivered instruction manual. It does not cover the consumable such as the LEDs and holder for storage bag.

During the installation of the equipment, the guarantee is invalidated in the following cases:

- Connections with invalid peripherals (electrical power supply, connections of the equipment not envisaged).
- Use, maintenance or repair by a not competent personnel.
- Use of spare parts and accessories not approved by MacoPharma.

The period of guarantee runs starting from the date of emission of this delivery form, for one year duration.

The delivery of the goods is under the responsibility of *MacoPharma* when this one is carried out by a forwarding agent approved by *MacoPharma*. In the other case this one is under the responsibility of the purchaser.

MacoPharma guarantees the supply against any design defect or construction affecting the MacoTronic B2 equipment.

The guarantee of *MacoPharma* is strictly limited, with the choice of *MacoPharma*, to the repair or the replacement of parts which are recognized defective and at the expenses of labor except transport costs and packing.

The replaced defective pieces become again the property of *MacoPharma*.

The repair, the modification or the replacement of parts for the period of guarantee cannot cause to prolong the warranty period.

For this guarantee, the user will have to present to *MacoPharma*, within 15 days a complaint as well as the delivery form.

The repairs, modifications or replacements required in consequence of the normal wear, of deteriorations or accidents coming from operator's errors, of defect of maintenance, lack of care, overloads, as well as shocks, falls, or degradations due to the non-conform use are not covered by the guarantee.

This guarantee will cease immediately in the event of replacement or of repair of the original parts by people not approved by *MacoPharma*.

Within the limits permitted by the applicable laws, it is of express convention that the guarantee stipulated in this paragraph is the only implicit guarantee, express or legal, that *MacoPharma* concedes on the sold equipment, and that, except written contrary provision, the purchaser gives up any action that the purchaser (or his employees, affiliated companies, successors or dealers) could have against *MacoPharma*, his employees, affiliated companies, successors or dealers, because of the sold materials; are aimed without limitation, the actions concerning the accidents with the people, damage with goods distinct

from the object of the contract, losses or consequential damages or immaterial and in particular, loss of use or of profit, loss of bags, stored products, etc.

The spare parts will have to be used under the operating conditions defined by MacoPharma.

The application of this guarantee is carried out according to the terms of the general terms of sale of *MacoPharma*.

#### LIMIT OF RESPONSIBILITIES

In no circumstances *MacoPharma* could be responsible for any damage, including, without limitations, of the damage for loss of products, interruption of work, loss of information, defect of the *MacoTronic B2* equipment or its accessories, physical injuries, waste of time, financial loss or material or for any indirect effect or consecutive of loss occurring within the framework of use, or impossibility of use of the product, even if *MacoPharma* would have been advised such damage.

#### **PROPERTY RIGHTS**

The integrated software in the memory of the equipment object of this handbook, including the handbook and the related document there, are entrusted to the user in license. They are the property of *MacoPharma* and are protected by the author's rights, all rights reserved. This integrated software can function only on one equipment at the same time and can be used only on the material to which it is built-in. This software cannot be separated from the hardware provided by *MacoPharma* or be distributed, reproduced, translated, disassembled, decompiled, analyzed, adapted, modified, incorporated or combined with another software except the cases authorized by the law.

GENERAL PRESENTATION

## DESCRIPTION

#### Purpose of the equipment

The *MacoTronic B2* equipment is used for the illumination of plasma bags according to the *THERAFLEX MB-Plasma* procedure.

Only bag systems for THERAFLEX MB-Plasma treatment provided by MacoPharma (BSV, BRJ, ZDV, SDV, SRV, SPV, JPJ series) must be used in combination with the device. MacoPharma is excluded from all liability or responsibility for any other non-specified use.

The *MacoTronic B2* is an illumination device with the following characteristics:

- Completely embedded computer-controlled illumination process.
- Capacity of 2 bags per cycle.
- Double-side illumination system using LED technology (2 panels of 24 LED per bag position).
- Control of energy supplied by each panel (by photo-diode).
- Temperature management inside illumination chamber using laminar air flow (fans) with monitoring by pyrometer for each bag.
- Data traceability (bag identification, light intensity, energy delivered, time, temperature).



Figure 1
The *MacoTronic B2* equipment, drawer opened.

#### PLACE OF USE

The MacoTronic B2 equipment has to be installed in clean room, on a fixed support being able to support a total load corresponding to the double of the weight of the MacoTronic B2

equipment (54 kg). The *MacoTronic B2* equipment has to be connected to the mains (110-240 VAC, 50/60 Hz, 750W), and if required, to peripheral equipment (Ethernet connection for report printer, USB connections for Barcode printer and Barcode reader).

## MAIN CHARACTERISTICS

The equipment main characteristics are:

Item	Description
AC power supply:	110-240 VAC, ~50/60 Hz
Electrical consumption:	750 W
Weight:	54kg
Noise level:	57dBa
Overall dimensions:	See next figure.
Communication outputs:	Ethernet connection for report printer
	USB connection for barcode reader.
	USB connection for Barcode printer.
	USB connection (if required)

The detailed characteristics are listed on page 122.

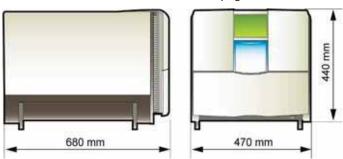


Figure 2
Overall external dimensions.

#### LOCALIZATION OF THE EXTERNAL DEVICES

#### Front side

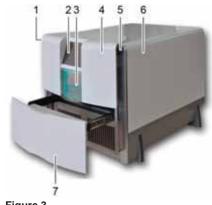


Figure 3
The front side.

#### Item Description

- Front USB connectors. Also used for the barcode reader connection.
- LCD display.
- 3. Power on indicator:
  - Steady blue when normally working.
  - Blinking when illumination ended (low frequency) or faulty (high frequency).
- 4. Front panel.
- 5. ON push button.
- 6. Cover.
- 7. Illumination drawer.

#### Rear side



Figure 4
The rear side.

#### Item Description

- Manufacturer label. See Label paragraph.
- Fuse sockets (F10AL250).
- 3. Power supply socket (110-240 V AC).
- 4. Fan outputs (upper electronic).
- 5. Fan outputs (upper drawer).
- 6. Ethernet socket (RJ 45).
- 7. USB sockets. Front top to bottom:
  - Bar code reader (if not connected on front side) or USB key.
  - Bar code printer.
- 8. Seal. Guaranty void if broken.
- 9. Fan outputs (lower drawer).
- 10. Fan outputs (illumination chamber).

#### Label

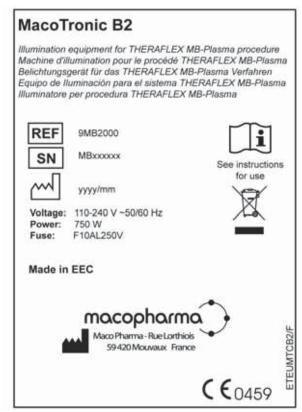


Figure 5
The manufacturer label.

Item	Description
REF	Equipment type.
SN	Equipment serial number.
$\sim$	Date of manufacturing.
Voltage	Minimum and maximum input voltages power supply frequency.
Power	Maximal energy consumption.
Fuse	Type of fuses to be used (F10AL250V). Respect these values.
i	Indicates that the reading of the user handbook is mandatory before using the equipment.

#### See instructions for use



Indicates that the equipment should be recycled in order to preserve the environment.



Mandatory
marking of
conformity,
indicating that this
industrial product
respect all the
essential
requirements of
safety mentioned
in MDD 93/42/ECC
European
directive.

## PERIPHERAL EQUIPMENT



Only the equipment here listed or any equipment provided exclusively by *MacoPharma* may be used. The use of accessories and cables other than those specified (including the maximum length for cables) can involve dysfunction as well as increase in the emission and/or reduction in the immunity of the apparatus.

All equipment connected to the system must be certified to IEC 950 standards or IEC/ISO applicable to equipment.

#### BARCODE READER

The barcode scanner allows the user to easily target the desired barcode and complete data transmission with a simple press of a button. In addition, when the scanner senses a barcode, the laser beam automatically switches to scan mode and activate CodeGate to ensure high-speed scanning and accuracy.



The barcode scanner must be connected to the dedicated *MacoTronic B2* output on front side or on back (See paragraph *Rear side*, on page 16).

Figure 6



The barcode reader.

Pictures may differ from delivered equipment

#### Item Description

- Laser window aperture.
- Mode select button/CodeGate button.
- 3. Red LED (scanner status).
- 4. Cable unlocking.
- 5. Green LED (scanner status).
- 6. Bipper (adjustable tone)
- 7. USB cable and connector.

#### General data

#### **Purpose**

hand-held laser scanner.

#### Operational

Laser source: Red LED @ 610-650 nm.
Resolution: Maximum 0.102 mm/4mils

#### Mechanical

Overall dimensions: 17 x 7.1 x 6.6 mm (6.7 x 2.8 x 2.6 in)

Weight: 121.9 g (4.3 oz)

#### **Electrical**

Current: Operating: 340mA @5VDC

Stand By: 190mA @5VDC

Input voltage: 5 VDC +/- 10%

#### **Environmental**

Operating temperature: use in air-conditioned room at 0 to +50°C (0 to +122°F)

Operating humidity: 5 to 95 % relative humidity, non-condensing.

Note: for more detailed data, refer to the manufacturer manual.

#### **BARCODE PRINTER**

The barcode printer, also called label printer, is used to print the label with illumination result at the end of the cycle.



Figure7
The barcode printer.

Pictures may differ from delivered equipment



The barcode printer must be connected to the dedicated *MacoTronic B2* output. See paragraph *Rear side*, on page 16.

Note: for more detailed data, refer to the manufacturer manual.

#### REPORT PRINTER

The report printer is used to print illumination report at the end of the cycle.



The report printer must be connected to the dedicated *MacoTronic B2* output. See paragraph *Rear side*, on page 16.



Figure 8
The report printer.

Note: for more detailed data, refer to the manufacturer manual.

Pictures may differ from delivered equipment

## PC COMPUTER

This PC is not mandatory. It will be used to run the *MacoTrace* application.

# Purpose Run the MacoTrace application if several MacoTronic B2 units are connected to a same Ethernet network. Characteristics

Refer to MacoTrace manual.

## QUICK START GUIDE

## **QUICK START**



This chapter, named *Quick start* summarized the various possibilities of the equipment. Use this chapter only after having fully read and understand this entire document.

MacoPharma cannot be responsible, in any way, for consequences of actions taken without having followed the safety procedures described in the others pages of this document.

#### BEFORE SWITCHING ON THE MACOTRONIC B2



Figure 9
Checking of the presence of left bags.

- 1. Open the drawer and check that no bag has been left inside the drawer.
- 2. Close the drawer.

#### SWITCHING ON THE MACOTRONIC B2



Figure 10 The ON switch.

Note: cables are to be connected as indicated on page 39.

- Power on the peripheral equipments (label printer, log printer, PC computer).
- 2. Check that the drawer (marker 2) is correctly closed.
- On the MacoTronic B2 equipment, push the ON button (marker 3) and release it.

The front lights go up (blue continuous light) (marker 1).



Figure 11

4. The initializing screen appears during the *MacoTronic B2* initialization procedure.



Figure 12 The login screen.

- 5. After the initializing the login screen is displayed.
- 6.The MacoTronic B2 equipment is ready to be used.

#### USER'S IDENTIFICATION



Figure 13 Selecting of the user's name and password

#### User selection

- 1. Touch the icon until your name is displayed...
  - ... or touch the ▼ icon to display all the authorized users and select your name.
- 2. Touch the icon and enter the corresponding password on the keyboard shown on the screen.
- 3. Touch the icon to display the next screen.

#### POSITIONNING THE BAGS



Figure 14
The two holders are placed in the drawer.

- 1. Open the drawer.
- Place the first pack in its holder and set the holder in on the left side of the drawer.
- Place the second pack in its holder and set the holder in on the right side of the drawer.

#### SCANNING THE PLASMA PACKS



Figure 15
The screen is waiting the Donation number scan.

The current screen is as represented on the figure on the left.



Figure 16 Scanning of the first bag.

- 1. Scan the first bag *Donation* code.
- 2. Scan the first bag *Product* code.
- Scan the first bag Lot code.
   The second bag screen is then displayed.
- 4. Scan the second bag Donation code.
- 5. Scan the second bag Product code.
- 6. Scan the second bag Lot code.
- 7. Touch the icon to display the next screen.



Figure 17
The screen waits for the drawer closing.

8. The waiting screen is displayed.

9. Close the drawer.

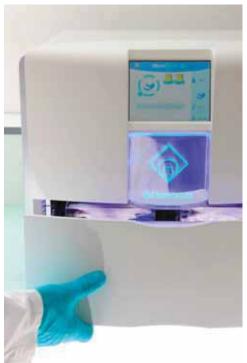


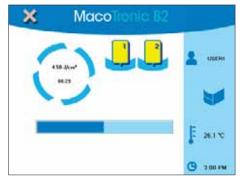
Figure 18
Closing the drawer.

## LAUNCHING THE ILLUMINATION



Figure 19
The waiting screen with is blinking triangle.

1. Touch the () icon.



2. The illumination cycle is launched as soon as the timer located inside the ring starts.

Figure 20
The screen during an illumination cycle.



3. Illumination automatically stops for each unit, once the quantity of energy defined by *THERAFLEX MB-Plasma* procedure is reached.

Figure 21
The screen at the end of an illumination cycle.

#### BARCODE LABEL PRINTING AND BARCODE CHECKING

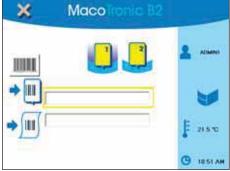


Figure 22
The first label screen.

Note: this paragraph is to be followed only if this function has been activated. If not, continue on paragraph Printing the report.

- At the end of the cycle, the label for bag 1 is automatically printed, stick it on bag 1.
- 2. The label screen is displayed. See figure on the left.



Figure 23
Scan of donation barcode.

- Scan the bag donation barcode in the first field.
- Scan the label barcode in the second field.

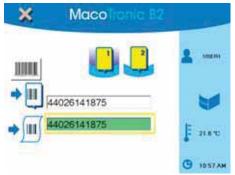


Figure 24
Scanning and printing of the bag labels.

- 7. Repeat the steps 3 to 6 for the second bag.
- 8. If the procedure cannot be finished properly press the icon to abort it.

#### PRINTING THE REPORT

A report is normally automatically printed.

#### EXTRACTING THE ILLUMINATED BAGS



Figure 25
Extracting the bags.

1. Open the drawer (if not yet opened) and remove the illuminated bags.

#### SWITCHING OFF THE EQUIPMENTS



Figure 26
The welcome screen.

- Power off the peripheral equipment's (label printer, log printer, PC computer).
- 2. If the icon is not displayed, touch the icon.



Figure 27
The OFF soft button.

3. Touch the oicon.



Figure 28
The screen waits the confirmation of the shutdown.

- 3. In the opened window, touch the corresponding button.
  - No: abort the shutdown procedure and return to the Donation screen.
  - Yes: shuts down the equipment. Note: the front lights turn off, the system shuts down, and the screen goes black. It takes then about two minutes to completely shut down the machine (fan stop), until the internal MacoTronic B2 temperature goes below the preset temperature.

# SETTING-UP

# TRANSPORT, STORAGE AND UNPACKING

## **TRANSPORT**



Figure 29
The transport case

The equipment is shipped on a wooden pallet with a carton cover especially designed to ensure its integrity during transport.

### CONTROLS DURING THE UNPACKING

During the reception, initially check the external integrity of the case and then the presence of all the elements listed in the *Packing list*.

Using this document, follow attentively all the described steps and check the presence of all the parts. Once the document completed, it will be returned to *MacoPharma*.

If a problem occurs during the checking, note the problem and contact the local *MacoPharma* representative or *MacoPharma*.

If all is in conformity, the *MacoTronic B2* equipment could be unpacked. A technician approved by *MacoPharma* will have to install the equipment.

The MacoTronic B2 equipment will carefully be unpacked near its place of installation.

#### Packing content

Packing contains the elements described in paragraph Delivered equipment, on page 3.

All these components will have to be controlled before beginning the installation.

#### Packing materials

After having checked the contents of the transport packing, the installation can be carried out as indicated in the following chapter.

MacoPharma advises the conservation of the transport packing. This one can be re-used to dispatch the MacoTronic B2 equipment to another laboratory, in the event of removal or for the return of the MacoTronic B2 equipment to MacoPharma for a repair.

If the elimination of materials of packing is decided, it will be necessary to take account of the legislation of the country and the rules of the laboratory.

#### Storage

The storage of the *MacoTronic B2* equipment is carried out in its packing of transport. The temperature and the moisture of the storage zone must remain under normal operating conditions (+10°C < temperature < 45°C and 10 < moisture < 80%). The packing of transport has to be protected from any environmental risk (water, gas, dust, shock, etc.).

#### Displacement

The *MacoTronic B2* equipment can be moved from the laboratory in which it was initially installed, in the case of a transfer to another laboratory or building.

MacoPharma is not responsible for the damage or the accidents caused by the users.

To take out the MacoTronic B2 equipment of the service, follow the following procedure:

- Preserve the database of the results of preceding treatments.
- Switch the *MacoTronic B2* equipment off.
- Remove the power plug.
- Remove the used connections (Ethernet, printers, barcode reader).
- Clean the internal drawer.
- Place the wood transport casing near the *MacoTronic B2* equipment.
- Install the MacoTronic B2 equipment in the wood transport casing.
- Place all the accessories and documents provided with the *MacoTronic B2* equipment in the wood transport casing.

The above procedure is also applicable to dispatch the *MacoTronic B2* equipment to the retailer or to the *MacoPharma* technical center for maintenance purpose.

## ON SITE PREPARATION

#### SAFETY REQUIREMENTS

MacoPharma recommends scrupulously following the rules of the company and the country, in particular:

- Safety regulations for the users handling of the products, etc.
- The installation of an adapted laboratory ventilation, reducing the local temperature.

MacoPharma is not responsible for problems involved in the installation by user (escapes, ventilation, etc). All actions will have to be taken in accordance with the rules of the laboratory and under the responsibility of the use.

#### **EQUIPMENT TO BE PROVIDED**

The following equipment will be necessary for the use of the MacoTronic B2 equipment:

- An electrical power supply (110-240 V AC, 50/60 Hz, 10 A + earth).
- A barcode reader.
- A barcode printer.
- A report printer.
- A computer (PC) if the *MacoTrace* application is used.



Only the equipment listed above or any equipment provided exclusively by *MacoPharma* may be used. The use of accessories and cables other than those specified (including the maximum length for cables) can involve dysfunction as well as increase in the emission of the apparatus.



All equipment connected to the system must be certified to IEC 950 standard or IEC/ISO applicable to equipment.

#### **WORKING AREA**

The working area requires the presence of:

- The MacoTronic B2 equipment.
- Windows ® PC computer; the computer features are specified on page 19.

#### Laboratory

The MacoTronic B2 equipment requires the following operating conditions:

- Controlled room temperature: + 20°C ±2°C.
- Ambient air humidity: 80% maximum without condensation.

#### Working area

- Working bench: it will have to support the weight of the *MacoTronic B2* equipment with important safety margin. In addition, the surface of the working bench will have to be compatible with the used products (resistance to the possible chemical aggression when cleaning, etc).
- MacoTronic B2 equipment: peripheral space will have to allow the opening of drawer as well as the access to various rear connections and the mains socket (for complete switch off). Thus, the working area will have to be sufficiently vast to ensure a good mobility around the MacoTronic B2 equipment; this is important both for the users and the ventilation of the MacoTronic B2 equipment (at least 20 cm space behind).
- MacoTrace computer: peripheral space will have to allow the use of the mouse and the keyboard in accordance with the usual ergonomic recommendations.

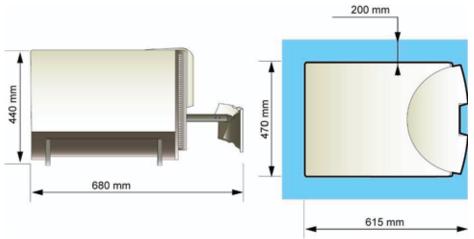


Figure 30 The working area.

#### Power supply wall sockets

The following power supply socket should be available:

Item	Description
MacoTronic B2 AC power supply:	1 wall socket (110-240 V, 10 A, + earth)
Report printer AC power supply (*):	1 wall socket (110-240 V, 2 A, + earth)
Barcode printer AC power supply (*):	1 wall socket (110-240 V, 2 A, + earth)
PC computer AC power supply (*):	1 wall socket (110-240 V, 2 A, + earth)
PC computer screen AC power supply(*):	1 wall socket (110-240 V, 1 A, + earth)

<sup>(\*)</sup> if used.

#### Ethernet wall socket

Item	Description
Ethernet (*):	1 RJ45 wall socket

(\*) if used.

#### Electromagnetic interference

The tests carried out on this instrument demonstrate conformity with the standard EN 61326-1-2006Class A equipment. These limits are conceived to ensure a reasonable protection against interferences detrimental to a general laboratory installation in a blood center (not intended to be used in a residential environment).

#### Radio frequency identification device (RFID)

When the instrument is equipped with this option, it includes two integrated readers emitting 13.56 MHz. Although the distance from emission is very weak (a few centimeters), check that there is no risk of interference with other equipment.

#### Transportation

Figure 31



The *MacoTronic B2* equipment transportation should be carried out by two persons.

Two persons are required to safely carry the machine.

The machine should be handled with two hands as showed on the picture and on both sides.

Exercise caution, the equipment weight is around 54 kg.

# **CONNECTIONS**

## GENERAL CONNECTION SCHEME

At the end of this chapter, the *MacoTronic B2* equipment will be connected to the various peripheral equipments as presented in the following figure.



Mains sockets
 Figure 32
 The general connection scheme.

## MACOTRONIC B2 CABLES



Connect the following cables onto the rear connectors of the *MacoTronic B2*:

- 1. Mains socket
- Ethernet for the report printer (if used)
- And 4. USB cable for barcode printer and barcode reader (if used)

Figure 33
The *MacoTronic B2* connectors to cables.

### Connection of the report printer cable (Ethernet)

Use this connection if a report printer is requested.

Use this connection if single *MacoTronic B2* equipment is used. Otherwise, this printer will be connected a switch connecting the printer, the machines and the computer running the *MacoTrace* application.

Connect the *MacoTronic B2* equipment *report printer* output to a report printer Ethernet socket..



The report printer must be connected to the dedicated MacoTronic B2 output.

Use this connection if several *MacoTronic B2* are connected to a single computer running the *MacoTrace* application.

Connect the *MacoTronic B2* equipment Ethernet output to the Ethernet network socket via a specific Ethernet cable.

#### Connection of the barcode printer cable

Connect the *MacoTronic B2* equipment *Barcode printer* output to the barcode printer USB socket via an USB cable.



The barcode printer must be connected to the dedicated *MacoTronic B2* output and through the delivered specific adapter.

#### Connection of the barcode reader cable

Use this connection if the RFID reader is not used.

Connect the *MacoTronic B2* equipment *Barcode reader* output to the barcode reader USB socket via the specific delivered cable.

The Barcode reader can be connected either on the front USB socket or on the back USB socket.



The barcode reader must be connected to the dedicated *MacoTronic B2* output and through the delivered specific cable.

## POWER SUPPLY CONNECTION

Connect the following power supply cables to the equipment and to the wall socket:

#### To mains socket



**Figure 34** The *MacoTronic B2* power supply connections.

To mains socket



Report printer



- MacoTronic B2.
- Report printer (if used).\*
- Barcode printer (if used).\*

Use

## STARTING-UP

## BEFORE SWITCHING ON THE MACOTRONIC B2



Figure 35 Checking of the presence of left bags.

1. Open the drawer and check that no bag has been left inside the drawer.

### SWITCHING ON THE PERIPHERAL EQUIPMENTS

 If necessary, power on the peripheral equipment's (label printer, log printer, PC computer).

## SWITCHING ON THE MACOTRONIC B2



Figure36
The On switch.

- Check that the drawer (marker 2) is correctly closed.
  - An opened drawer inhibits the checking procedure.
- On the MacoTronic B2 equipment, push the On button (marker 3) and release it.

The front lights go up (blue continuous light) (marker 1).



Figure 37
The initialization screen.



Figure 38
The login screen.

3. The initializing screen appears during the *MacoTronic B2* initialization procedure.

Messages are displayed in the center zone according to the initializing process.

If an error occurs during the start-up, check first the eventual presence of a bag into the drawer.

- 4. After the initializing the login screen is displayed.
- 5.The *MacoTronic B2* equipment is ready to be used as described on page 48.

## **SETTING THE WORKING PARAMETERS**

Before using the *MacoTronic B2* equipment, the authorized user (administrator) should set the equipment parameters as described in chapter *Settings*, on page 74.

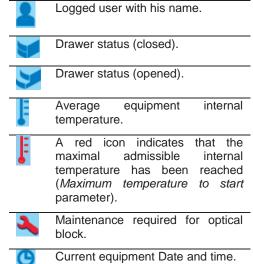
## ICONS DISPLAYED ON THE SCREEN

The following tables show the various icons which can be displayed onto the various screens.

#### Right screen side



Figure 39
The icons on the right side of the screen.



## Icons displayed during the illumination cycle

Icon	Meaning
	Bag fully identified and being treated or ready for treatment
	Bag not identified, it won't be treated
	Bag successfully treated
10	Bag unsuccessfully treated; an error occurred during the treatment

## PREPARING THE ILLUMINATION

## **USER'S IDENTIFICATION**



The *MacoTronic B2* equipment has been switched on according to chapter *Starting up*, on page 44.

According to the *MacoTronic B2* configuration (see paragraph *Manage user*, on page 80), the user can be selected on the main screen by:

- Manual entry of the user's name and password.
- Scanning the user's name and password.

#### Manual entry of the user's name and password



1. Touch the cicon until your name is displayed...

... or touch the arrows to scroll the user list up and down

Figure 40 Selecting your name.



Figure 41
Entering the corresponding password.

- 2. Touch the icon and enter the corresponding password on the keyboard shown on the screen.
- 3. Touch the icon to display the next screen.

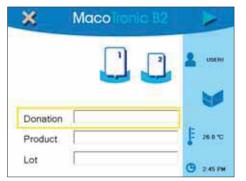


Figure 42
The screen waits the bag code entries.

# 4. The screen waits the bag code entries.

Follow on paragraph *Opening the drawer*, on page 50.

#### Scanning the user's name



This procedure can be done when the corresponding choice has been selected on *Barcode* in the configuration settings. In the *User management* menu, set the *Manage user* choice onto *Barcode* choice (see paragraph *Manage user*, on page 80).



Figure 43
The screen waits for the user's identification scanning.

- 1. The *MacoTronic B2* screen is as shown on the left figure.
- 2. Scan your identification number.



Figure 44
The screen waits the bag code entries.

As soon as the code scanning is validated, the screen waits the code entries.

Follow on paragraph *Opening the drawer*, on page 50.

## OPENING THE DRAWER

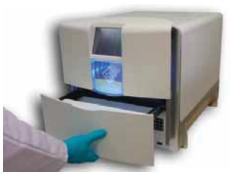


Figure 45
Opening the drawer.

- Before opening the drawer, check that there is nothing which could obstruct the movement.
- With caution, open the drawer of the MacoTronic B2 using the handle on lower part of the front panel.



If the drawer doesn't open, it means that it is automatically locked by software (illumination cycle running or auto test in progress).

## PLACING THE PLASMA PACKS

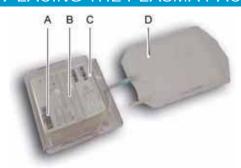


Figure 46
Positioning the bag and the holder.

 Set the pack (marker C) in the holder (marker B) as indicated on the figure on the left.

Place the bag (marker D) on a flat position.

The barcode (marker A) must be clearly visible for the scanning.



Figure 47
Detail of the positioning.

Check the correct positioning of the tube (marker A) at the holder exit.



Figure 48
Placing the first holder in the drawer.

Place then the first pack and its holder on the left side of the drawer as indicated on the figure on the left.



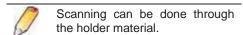
Figure 49
Placing the second holder in the drawer.

- 3. Repeat the step 1 for the second pack.
- 4. Then, place the second pack and its holder on the right side of the drawer.

## SCANNING THE PLASMA PACKS



Figure 50
The screen is waiting the Donation number scan.



The screen is as represented on the figure on the left.



Figure 51 Scanning of the first bag.

 Scan the *Donation* code on the first bag.

The screen waits for the Donation

If the scan is immediately erased, a false

As soon as the scan has been validated, the cursor automatically jumps into the

Maco fronte B2

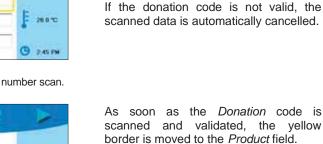
Donation

Product

Lot

© 2-45 PM

Figure 52
The screen is waiting the *Donation* number scan.



next field.

number scanning.

entry has been detected.



Figure 53
The *Donation* code has been scanned.

In case of reading error, click on to go back to the previous field or to jump to

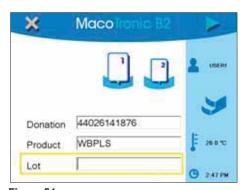


Figure 54
The *Product* code has been scanned.

# 2. Scan the *Product* code on the first bag.

the next one.

If the scan is immediately erased, a false entry has been detected.

The cursor automatically jumps into the next field.

If the product code is not valid, the scanned data is automatically cancelled. Note: the *Product* code field is displayed only if the corresponding parameter has been set. See *Options* menu, *Product code* paragraph, on page 88.



In case of reading error, click on to go back to the previous field or to jump to the next one.



Figure 55 The Lot code has been scanned.



4. Check that the first bag icon is yellow. This indicates that the data has been correctly scanned and validated.

3. Scan the Lot code on the first bag.

previous screen.

entry has been detected.

screen.

If the scan is immediately erased, a false

Note: this screen is not visible as the application immediately shows the next

In case of reading error, click

on 🔀 to go back to the

5. If no other bag is to be illuminated, directly continue to step 6. For the second plasma bag, proceed as per steps 1 to 4 above.

Maco Donation Product Lot

Figure56

The second set of screens, relating for the second bag is displayed.

- 6. Touch the icon to display the next screen.
- Maco

Figure 57 The screen waits for the drawer closing.

## 7. The waiting screen is displayed.

Note: the drawer is still open as indicated by the icon

## CLOSING THE DRAWER



Figure 58
Closing the drawer.

 Before closing the drawer, check that there is nothing which could obstruct the movement.



Check the position of the bag tubes. If the scanner is connected onto the front USB connector, check that the scanner cable will not obstruct the drawer closing.

With caution, close the drawer of the MacoTronic B2 using the handle on lower part of the front panel.



Figure 59
The waiting screen with its blinking triangle.

3. The *MacoTronic B2* is ready to start an illumination cycle.

The icon is blinking. Continue on chapter *Starting an illumination*, on page 56.



The drawer is locked and can't be manually opened, due to the presence of an electromagnet. To open the drawer, touch the icon; the bags can be rescanned, as they have not been treated.

## LAUNCHING AN ILLUMINATION

According to the *MacoTronic B2* configuration (see paragraph *Options menu*, *Illumination start after scan* paragraph, on page 90), the illumination starting is:

- Manual, the user is launching the illumination.
- **Automatic**, the illumination starting is automatic as soon as the drawer is closed.

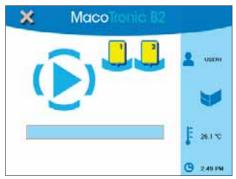


No illumination cycle will be launched until the inside temperature of the system is correct.

### MANUAL LAUNCHING



To change to an automatic illumination launching, see paragraph *Options menu*, *Illumination start after scan* paragraph, on page 90),



**Figure60** The waiting screen with is blinking triangle.

- 1. The screen is as per figure on the left.
- 2. Touch the () icon.

A new screen is displayed.

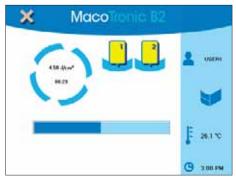


Figure 61
The screen during an illumination cycle.

The illumination cycle is launched as soon as the timer located inside the ring starts.

If an error occurs (bag misplaced, etc.), the corresponding error message is displayed. In this case, refer to Errors Message section before any other action regarding the bag.

In the rotating ring, data is continuously updated.

The displayed information is as follows:

0.86 J/cm*	Current quantity of delivered energy defined as per THERAFLEX MB- Plasma procedure for the selected bag
08:09	Current illumination duration (minutes:seconds).
_	Visual indicator of the current illumination duration
	Bag selected
2	Bag not selected

At any moment of the cycle, or after the termination, it is possible to visualize the graph of the illumination cycle for the considered bag.

To display this graph, touch the corresponding bag icon ( ).

The displayed information is as follows:

Donation:	Scanned data.
Product:	Scanned data.
Lot:	Scanned data.
23.7 °C	Current bag temperature.
164.78 mW/cm <sup>2</sup>	Current bag light intensity.
120.35 J/cm <sup>2</sup>	Current bag energy received.

To close this graph, touch the corresponding bag icon ( ).

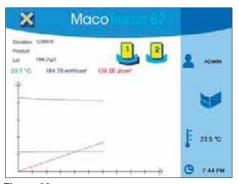


Figure 62
The graph screen at the end of a normally finished illumination cycle.



If the temperature exceeds the maximum defined temperature during an illumination (see page 84)a warning message appears on the screen and in the report. The labels will still indicate *Plasma treated with MB*.

The warning temperature threshold of bag corresponds to a warning level. When the temperature of the plasma bag measured by the pyrometer is above the programmed value, an alarm occurs. It is recommended to fix it at 26°C. In all cases the cycle remains valid if the required energy is delivered.

If the temperature is exceeded during the cycle, the temperature is printed in red on the report. It is just a warning, the plasma temperature is high and may affect the quality of the plasma but the *THERAFLEX* procedure is still valid. The corrective action is to check that the machine is well located according to the user's manual recommendations. And that the plasma temperature was not too high when placed within the machine.

Note that if the warning occurs during a cycle the maximum temperature reached during a cycle will be written in red on the report.

The user should analyze the amount by which the warning temperature was exceeded and determine the validity of the procedure by means of internal protocols.



At this step, it is possible to stop or abort the current illumination cycle. See page 59.

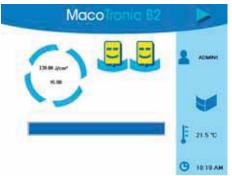


Figure 63
The screen at the end of a normally finished illumination cycle.

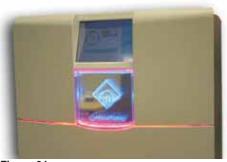


Figure 64
The front light status (steady, blinking) and light color are according to the illumination status. In this picture, the illumination is in progress.

#### Illumination automatically stops for each unit, once the quantity of energy defined by THERAFLEX MB-Plasma procedure is reached.

The screen shown on the left is displayed.

At the end of a normal illumination cycle the following icon status are:

120.06 J/cm²	Total quantity o delivered energy defined as pe THERAFLEX MB Plasma procedure.	/ r
11:58	Total illumination duration (minutes:seconds).	1
<u> </u>	Laughing icon.	
	Full dark blue visua indicator.	I

In the meantime, the front light status is as follows.

Color	Meaning
Steady	No illumination in progress.
Slow blinking	Correct illumination session ending.
Fast blinking	Incorrect illumination session.
Magenta	Illumination in progress.

#### It is then possible to print the barcode labels and check the barcode.

Proceed as per paragraph *Barcode label printing and barcode checking*, on page 62.

Note: this option should first be selected in the *Option* menu, choice *End illumination barcode control* activated (see page 91).

## STOPPING/ABORTING AN ILLUMINATION CYCLE

When an illumination has been launched it is possible to stop it.

 The illumination cycle being launched the screen is as on the figure on the left.

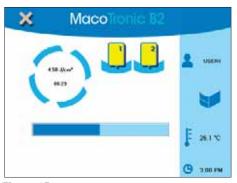
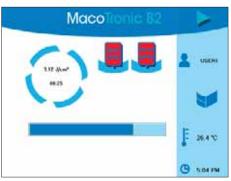


Figure 65
The screen during an illumination cycle.



**Figure 66**The screen waits the operator's decision.



**Figure67**The screen waits the operator's decision.

Stop the illumination cycle by touching the icon.

The screen is as on the figure in the left.

- 3. Touch:
  - to continue the currently paused illumination cycle.

YES to abort the current illumination cycle.

In this case, the screen shows the aborted icon(s). Touch the icon to follow the process.



An interrupted cycle cannot be restarted. The treatment of an interrupted cycle is not valid. Any partially-treated plasma is unusable.

## SAVING THE ILLUMINATION DATA

Once an illumination cycle is completed, a file is automatically created as follows:

MACHINE SERIAL NUMBER \_DATE\_ ILLUMINATION NUMBER FOR THE DAY.MT2

For example:

A003001\_05\_03\_2010\_007.MT2

represents the  $7^{th}$  illumination, carried out on  $5^{th}$  March 2010, on the machine with serial N° A003001.

All saved files are stored into the equipment memory and can be downloaded by USB key on setup menu; see paragraph <u>TRANSFERRING DATA</u>. on page 97. These files are not erased after equipment switching off.

# BARCODE LABEL PRINTING AND BARCODE CHECKING



The barcode label printing and barcode checking screen is displayed, only if this functionality has been activated (*Option* menu, choice *End illumination barcode control* activated; see page 91).

If not, continue on next chapter, on page 68.

This step is used to crossmatch the original barcode and the one which will be printed. This manipulation can avoid printing problems and allows the user to ensure that the printed label has been stuck on the right bag.

An option allow you to choose the label will be printed automatically or if you have to scan the original barcode to trigger the printing of the label. This option is called "Auto Print Label" and can be configure in Print section of the settings menu.

## OPERATING MODE WITH AUTO PRINT LABEL ENABLED

In this case the label is printed automatically and you just need to do the crossmatch.

Proceed as follows.

- 1. A the end of the label the label for bag 1 is automatically printed.
- 2. Stick it on bag 1.
- 3. The label screen is displayed. See figure on the left.

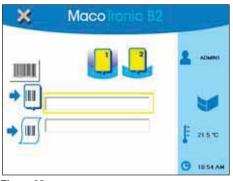


Figure68
The first label screen.



Figure 69
Scan of donation barcode.

4. Scan the bag donation barcode of the first bag.

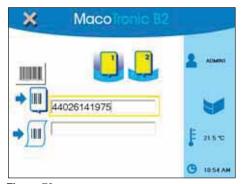


Figure 70
The first label has been scanned and printed.
The second label screen waits for the scanning.

- If the donation barcode is correct the data will be displayed in field one and the yellow selection rectangle moves to the second field.
- If the donation barcode is not correct the data will be automatically erased and the yellow selection rectangle won't move.



Figure 71
The two scans have been done.

- 7. Scan the printed label.
- If the printed label barcode is correct the field background will change to green, the label screen for bag two will be displayed and the label for bag 2 will be printed.
- If the printed label barcode is correct the field background will change to red.
- 10. If necessary, repeat the steps 3 to 6 for the second bag.
- 11. If the procedure cannot be finished properly press the continue on paragraph Ending the illumination cycle, on page 68.



## OPERATING MODE WITH AUTO PRINT LABEL DISABLED

In this case you need to scan the original donation barcode to print the label and then you can do the crossmatch.



1. The label screen is displayed. See figure on the left.

Figure 72
The first label screen.



first bag.

2. Scan the bag donation barcode of the

Figure 73
Scan of donation barcode.



Figure 74
The original label has been scanned once and printed. The crossmatch can be done

- If the donation barcode is correct the label is printed automatically and the next field is selected.
- 4 Stick the printed label on the bag.



Figure 75
The two first scan have been done.



Figure 76
The two first scan have been done.

Scan the original donation barcode again, if the scan is correct the last field will be selected.

- 6. Scan the printed label.
- If the printed label barcode is correct the field background will change to green and label screen for bag two will be displayed.
- If the printed label barcode is correct the field background will change to red.
- 9. If necessary, repeat the steps 3 to 6 for the second bag.
- 10. If the procedure cannot be finished properly, press the icon to abort it Continue on paragraph Ending the illumination cycle, on page 68.
- 11. If the label hasn't been printed at the end of the cycle you can reprint it by pressing the following button



## REMARKS

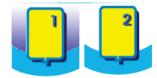


Figure 77
Bag 1 is currently processed.

1. The bag currently processed has a dark blue background; in the case bag 1.

See figure on the left.



Figure 78 Original barcode picture

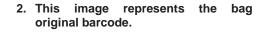




Figure 79 Label barcode picture



Figure 80 Yellow selection rectangle.

3. This image represents the barcode on the illumination result label.

- The yellow rectangle shows you which field is selected, in this example you have to scan the label barcode.
- If the barcode has not been printed, you can reprint it by pressing this button.





6 If the procedure cannot be finished properly, press the grey cross on the top left corner of the screen icon to abort it.

# **ENDING THE ILLUMINATION CYCLE**



This screen is displayed only if the *With end process screen* function as been activated. See paragraph *With end process screen*, on page 91). If not, the login screen is displayed (see Figure 40 on page 48).

# **OPERATING MODE**

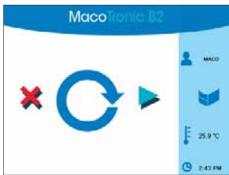


Figure 83
The choice screen.



Figure 84
Extracting the bags.

- 1. The choice screen is displayed. Refer to figure on the left.
- 2. Click on:



to display a new donation screen and continuing another illumination cycle with new bags. Proceed as per paragraph *Opening the drawer*, on page 50.



to close the session. A new user can then be logged. Continue as per step 4, on page 45.

3. Open the drawer (if not yet opened) and remove the illuminated bags.

# **SWITCHING OFF**

#### SWITCHING OFF THE PERIPHERAL EQUIPMENTS

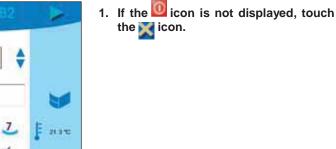
 If necessary, power off the peripheral equipment's (label printer, log printer, PC computer).

# SWITCHING OFF THE MACOTRONIC B2 EQUIPMENT

After the illumination process, the  ${\it MacoTronic~B2}$  equipment should be switched off as follows.



Figure 85 The login screen.



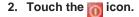




Figure 86
The OFF soft button.



**Figure 87**The screen waits the confirmation of the shutdown.

- 3. In the opened window, touch the corresponding button.
  - No: abort the shutdown procedure and return to the Donation screen.
  - Yes: shuts down the equipment.

    Note: the front lights turn off, the system shuts down, and the screen goes black. It takes then about two minutes to completely shut down the machine (fan stop), until the internal MacoTronic B2 temperature goes below the preset temperature.

# REPRINT REPORT OR LABEL

### REPRINT

At any time you can reprint the illumination label or the report for a bag.



Figure 88
The administrator screen

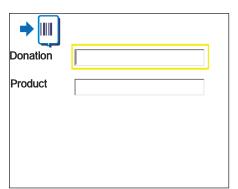


Figure 89
The retrieve bag screen.



Figure 90

- 1. Login as Administrator.
- 2. Click on the printer icon.

- 3. Scan the donation barcode.
- Scan the product code if needed.

To reprint a label, click on the barcode icon. To reprint a report, click on the printer icon.

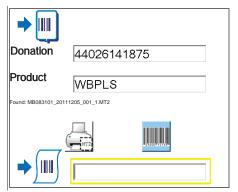


Figure 91

If you have printed a barcode then you need to perform the crossmatch by scanning the printed label.

 If the crossmatch is successful the field background will change to green, otherwise it will change to red.

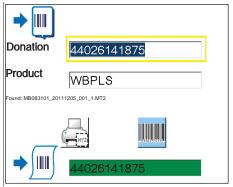


Figure 92

# REMARKS

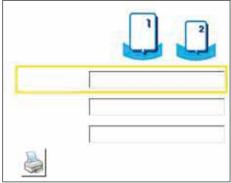


Figure 93
Reprint Menu access for user

 If option is enabled, users cannot access to the reprint menu by pressing the printer button in the bag identification screen.



SETTINGS

# **SETTING MENUS**

.

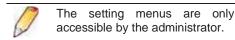
### AIM OF THE SETTINGS MENUS

The setting menus allow the setting of some functions of the *MacoTronic B2* equipment, such as the login method (by user name or by scanner), RFID detection, maximum and minimum allowed internal and bags temperatures, file transfer to or from an USB key, etc. These functions are detailed in the following chapters. Moreover, the paragraph *How to*, on page 78, summarizes the main actions which can be carried out by the administrator.

#### ACCESS TO THE SETTING MENUS







- 1. Login as an administrator
- 2. Enter the corresponding password.
- Click onto \_\_\_\_.



Figure 95 Selecting the Tools icon.





Figure 96
The Settings menu when displayed.

Figure 97
The Settings menu when displayed.



- 5. The Settings menu is displayed. The other icon functions are:
  - Return to the previous screen (Figure ).
    - Return to the previous screen (Figure).

 Click on the drop down list to display the available functions. Refer to paragraph Available settings below.

Function	See page
User management	80
Temperature	82
Print	86
Bag identification	88
Process	90
DM	92
Maintenance	94
USB	96

# NOTE CONCERNING THE BUTTONS

The buttons are presented with three possible states, as follows:

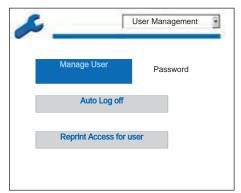
State	Background	Foreground	Meaning
<b>Function Name</b>	Grey	Grey	Non available function (disabled).
Function Name	Grey	Blue	Non activated function.
Function Name	Blue	Blue	Activated function.

# How to...

Action to be carried out	Paragraph name	See page
Automatic checking of bag presence	Check bags presence	90
Bag checking with Data manager	Check bags with DM	91
Bag label printing (end of illumination)	Barcode label printing	62
Bag presence detection (automatic)	Check bags presence	90
Barcode comparison	End illumination barcode control	91
Check bag with DM	Use of the DataManager software	91
COM port of the barcode printer	Bar printer COM port n°	87
Data Manager	With DM	91
Data transfer	Transferring data	97
End processus screen selection	With end processus screen	91
File transfer	Transferring data	97
Illumination starting after scan	Illumination start after scan	90
Password checking	Manage user	80
Print report mode (with/without graph)	Print report button	86
Printer (barcode printer). COM port	Bar printer COM port n°	87
Printer (Report printer selection)	Print report	86
Product code entering field	Product code	88
Report printer selection	Print report	86
RFID activation	With RFID	89
RFID presence	With RFID	89
Temperature (maximum of bag)	Warning temp. threshold of bag (°C)	84
Temperature (maximum to start)	Maximum temperature to start (°C)	84
Transferring data	Transferring data	97
USB key	Transferring data	97
USB transfer	Transferring data	97
User's name manual entry	Manage user	80
User's name scanner entry	Manage user	80

# **USER MANAGEMENT MENU**

#### **AVAILABLE FUNCTION**



The functions are described below.

Figure 98
The Settings menu when displayed.

#### Manage user

Click on this button to select one of the two choices:

- Password: at the beginning of an illumination cycle, the standard password screen will be shown. The user should enter his user's name and his password.
- **Barcode**: at the beginning of an illumination cycle, the password will be entered by scanning user's bare code.



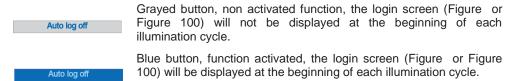
**Figure 99**When *Password* is selected, this screen will be displayed at the beginning of an illumination cycle.



**Figure 100**When *Barcode* is selected, this screen will be displayed at the beginning of an illumination cycle.

#### Auto log off

Define the display status of the login screen at the beginning of each illumination cycle.



#### Reprint Access for user

Define if the reprint button will be accessible for user

Grayed button, non activated function, the reprint button won't be accessible for user

Blue button, no activated function activated, the reprint button will be accessible for user

# TEMPERATURE MENU

The maximum temperature settings must be fixed according to the blood centre procedures. The temperature setups recommended below are defined taking into account that the machine is properly installed in an air-conditioned room below 21°C.

The two functions are described below.

### **AVAILABLE FUNCTION**

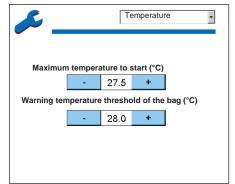
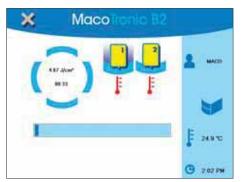


Figure 101
The *Temperature* menu.

MacoTronic B2 Rev 2

#### Warning temperature threshold of bag (°C)



**Figure 102**The *Warning temperature* threshold.

By clicking on the or buttons, select the maximal authorized temperature of the plasma bag, temperature measured by the pyrometer.

# In all cases the cycle remains valid if the required energy is delivered.

The warning temperature threshold of bag corresponds to a warning level. When the temperature of the plasma bag measured by the pyrometer is above the programmed value, an alarm occurs.

It is recommended to fix it at 26°C.

In all cases the cycle remains valid if the required energy is delivered.

If the temperature is exceeded during the cycle, the temperature is printed in red on the report. It is just a warning, the plasma temperature is high and may affect the quality of the plasma but the *THERAFLEX* procedure is still valid. The corrective action is to check that the machine is well located according to the user's manual recommendations. And that the plasma temperature was not too high when placed within the machine.

Note that if the warning occurs during a cycle the maximum temperature reached during a cycle will be written in red on the report.

	Illumination data	
	Source 1	Source 2
Energy programmed (J/cm²)	120	0.00
Energy delivered (J/cm²)	120.70	120.32
Maximum intensity (mW/cm²)	162.82	156.94
Duration (HH:MM:SS)	00:12:58	00:13:28
Warning temperature programmed (°C)	26.00	
Maximum temperature reached (°C)	27.80	28.30

# Maximum temperature to start (°C)

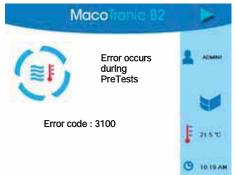


Figure 103

When displayed, this screen indicates that the "Maximum Temperature to start" threshold of bag value has been reached or exceeded and that you cannot start the cycle until the temperature goes under the threshold.

By clicking on the or buttons, select the maximal authorized temperature inside the illumination chamber above which the illumination cycle will not start until the temperature decreases below this programmed value.

It is recommended to set up this temperature to 24°C.

# **PRINT MENU**

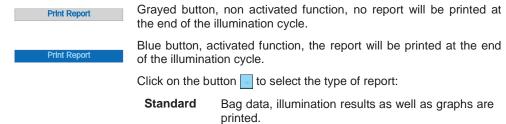
### **AVAILABLE FUNCTION**



Figure 104
The *Print* menu.

### Print report button

Define the display status of the login screen at the beginning of each illumination cycle.



Simple Sole the bag data and illumination results are

The four functions are described below.

printed without any graphs.

#### Print report

The printer selected is the windows default printer (in this cas Ghostscript PDF).

#### Bag label print button

Define the display status of the login screen at the beginning of each illumination cycle.

Bag label print

Grayed button, non activated function, no barcode label will be printed at the end of the illumination cycle.

Bag label print

Blue button, activated function, a barcode label will be printed at the end of the illumination cycle. On this label, are printed, the illumination status (*Invalid treatment* or *THERAFLEXtreated Plasma*), the date and time of illumination, the *MacoTronic B2* serial number, the lot number, the donor code, the bag location and the *file\_name.MT2* (MT2 being the file extension of the *MacoTronic B2* files).

MacoPharma recommends activating this function.

#### Bar printer COM port n°

By clicking on the or buttons, select the COM port on which the barcode printer is connected.

This is set up by the technician during the installation and may be changed if several printers are connected to the USB ports.

#### Test Print Button



Pressing this button will send a print test page to the label printer



Pressing this button will send a print test page to the report printer

# BAG IDENTIFICATION MENU

### **AVAILABLE FUNCTION**



The function are described bellow.

Figure 105
The Bag identification menu when displayed.

#### With Mask

This function enables the mask verification system for barcode format.



Grey button : disabled function , the system will accept any kind of barcode format

Blue button, activated function, the system will accept only barcode which have a format defined in the mask file.

#### Product code

This option allows the activation of the line *Product Code* in the *Bag Definition* window.

Figure 106 Figure 107

Product Code Product Code

The *Product code* line is activated (blue color)

The Product code line is inactivated (grey color)

#### With RFID

Activated, this option allows the bag identification with RFID tags.

Grayed button, non activated function, the *Product number* will not be asked during the bag scanning, before the illumination cycle. See step 2, in the *Scanning the plasma packs* paragraph, on page 51.

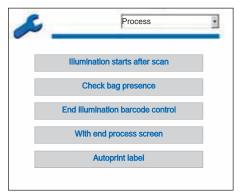
Blue button, activated function, the *Product number* will be asked during the bag scanning, before the illumination cycle. See step 2, in the *Scanning the plasma packs* paragraph, on page 51

Grayed button, non activated function, the bag code must be read by *MacoTronic B2* hand scanned.

Blue button, activated function, the bag code is read by the antenna integrated in the *MacoTronic B2*. Any manual scan is no longer available.

# **PROCESS MENU**

### **AVAILABLE FUNCTION**



The function are described bellow

Figure 108
The Process menu when displayed.

#### Illumination start after scan

Allow the illumination cycle launching as soon as the scans are done and after the drawer closing.

Illumination starts after scan

Grayed button, non activated function, the illumination cycle will be launched by the user by touching the launching the icon. See paragraph *Manual launching* on page 56.

Illumination starts after scan

Blue button, activated function, the illumination cycle will be automatically launched as soon as the scans are done and after the drawer closing, without touching the icon. See paragraph *Automatic launching* 

#### Check bags presence

Check the bag presence inside the drawer before authorizing an illumination cycle start.



Grayed button, non activated function, the blood bag presence is not checked before launching the illumination cycle.

Blue button, activated function, the blood bag presence is checked before launching the illumination cycle. If, at least, one bag is missing, the missing screen (Erreur! Source du renvoi introuvable., on page Erreur! Signet non défini.) is displayed.

#### With end process screen



This button can be activated only if, in the *User management* function (see page 81), the *Auto Log Off* button has been deactivated (grey button)

Activated, this option displays an end process screen.

With end processus screen

Grayed button and foreground indicates a non accessible function. To enable this function, open the *User management* function (see page 81) and deactivate the *Auto Log Off* button; it must be grey.

With end processus screen

Blue button, activated function, the choice screen (Figure ) is displayed.

With end processus screen

Grayed button and blue foreground, non activated function, the login screen (Figure) is directly displayed.

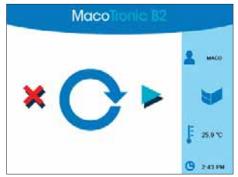


Figure 109
When the *With end processus screen* button is activated, this screen is displayed at the end of



When the *With end processus screen* button is not activated, this screen is directly displayed at the end of an illumination cycle.

#### End illumination barcode control

Activated, this option avoids errors that can occur during the reading and the printing of the label and allows verifications that the user has stuck the *MacoTronic* label on the correct bag.

End Illumination Barcode Control

an illumination cycle.

The function cannot be enabled because the label printing is not enabled

End Illumination Barcode Control

Grayed button, non activated function, the barcode comparison process between the original and the printed label is not requested.

End Illumination Barcode Control

Blue button, activated function, the barcode comparison process between the original and the printed label is requested at the end of the illumination (see page 62).

MacoPharma strongly recommends activating this barcode control function.

# **DM** MENU

# **AVAILABLE FUNCTION**

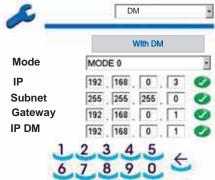


Figure 111
The *DM* menu.

This screen allows the configuration of the *Macotrace Data manager*.

You can configure:

- The Macotrace behavior.
- The machine network configuration

#### Macotrace behavior

The with DM button activated the *Macotrace* functionalities, please note that you have to restart the machine to finish the configuration.



Grayed button, non activated function, the *Macotrace* functionalities are disable

Blue button, activated function, the  ${\it Macotrace}$  functionalities are enabled

The mode drop down list allows you to select what will be the behavior of the *Macotrace*.

#### Mode\_0

The *Macotrace* B2 will transfer his status to the *Macotrace*,and the illumination file will be automatically imported in the *Macotrace* at the end of the cycle.

There is no verification on the bag identification data: a bag can be illuminated twice.

#### Mode\_1

The *Macotronic* B2 will transfer his status to the *Macotrace*,and the illumination file will be automatically imported in the *Macotrace* at the end of the cycle.

There is verification on the bag identification data: a bag cannot be illuminated twice.

#### Mode 2

The Macotronic B2 will transfer his status to the *Macotrace* and the illumination file will be automatically imported in the *Macotrace* at the end of the cycle.

There is verification on the bag identification data: a bag cannot be illuminated if he has not been declared before in the *Macotrace* imported from BBIS or during sterile connection.

#### Network configuration

You can configure the network settings of the *Macotronic B2* from this screen. The configuration will be applied during the next startup of the *Macotronic B2* if the DM option is activated, therefore you need to enabled the DM button and restart the machine to save the configuration.

#### IP/Subnet/Gateway:

Standard network configuration, set the *Macotronic* on the same network as the *Macotrace*.

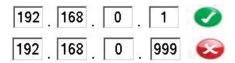
#### IP DM

Enter the Macotrace IP address

Please note that the software checks if the data entered are valid which means:

- IP / Gateway / IP DM: digits must be between 0 and 254, last digit cannot be 0
- Subnet: digits must be between 0 and 255.

If these rules are not followed a red cross will be displayed otherwise it will be a green mark



# **MAINTENANCE** MENU

# **AVAILABLE FUNCTION**



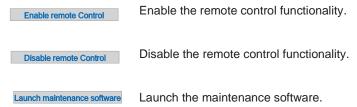
The function are described bellow

Figure112

The Process menu when displayed.

#### **Button List**

This button are not toggle button but action button, use it only if a *MacoPharma* representative request it.



# **USB** MENU

# **AVAILABLE FUNCTION**



Figure 113
The *Process* menu.

The icons are:

Eject USB

Deactivate the USB key before extracting it from the USB connector.



Select the language file for a transfer.



Select the illumination data file (.MT2) for a transfer.



Select the user list file for a transfer.



Select the parameter file for a transfer.



Select the mask file for a transfer.



Select the log file for a transfer.



Click on this button to transfer from the *MacoTronic B2* to the USB key the selected





Click on this button to transfer from the USB key to the *MacoTronic B2* the selected data



Picture of the used memory on the USB key.



Picture of the used memory on the *MacoTronic B2* internal memory.

# TRANSFERRING DATA

This function allows transfer of data from the *MacoTronic B2* to an USB key or from an USB key to the *MacoTronic B2*.

1. Insert an USB key into one of the USB connector.

The USB connectors are located:

- on the front face (see Figure 3, marker 5);
- or on the rear side (Figure 4, marker 6).
- 2. Click on one or several of these 6 icons ( ... ... ) to select the data to be transferred.

The selected icon(s) receive(s) a blue background ( ).



MacoTronic B2 to the USB key;
or on to transfer data from the USB key to the MacoTronic B2.

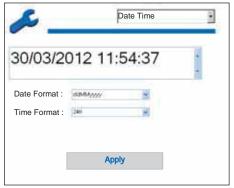
3. Check the transfer or the residual memory with the two animated scrolls.



Figure 114
The *Process* menu.

# DATE TIME MENU

# **AVAILABLE FUNCTION**



This screen is used to set the date/time value and format.

Figure 115
The Date Time menu when displayed.

#### Set the Date and time values

- To change the date and time, press the value that you want to change to highlight it in blue
- Then press the up and down arrow to increase or decrease this value.
- Then press the apply button to save the modification.



### Change the date and time format

To change the date or time format, open the corresponding list by pressing the blue arrow and select the desired value.

This display format will be used for the right menu, the report and the label

Date Format	Display
ddMMyyyy	day/month/year ie :
	30/03/2012 for 30 March 2012
MMddyyyy	month/day/year ie :
	30/03/2012 for 30 March 2012

Time Format	Display
12 H	hh:mm:ss tt
	le : 02:34:59 PM
24 H	HH:mm:ss
	le : 14 :34 :59

CURRENT MAINTENANCE

# CURRENT MAINTENANCE PROCEDURES

The current preventive maintenance actions cover the maintenance and the regular cleaning of the equipment, the users will have to carry out.



In addition, to assure safe, trouble free service, the *Macotronic B2* has to be serviced at least every 12 months by a qualified and certified technician according *MacoPharma* procedure (twice a year minimum is highly recommended in case of intensive use).

Every 24 months (or after 12 000 cycles), the 4 optical blocks have to be exchanged in order to recalibrate the integrated photocell and perform a complete LED aging control.

### HARDWARE REQUIREMENTS

Before carrying out the current maintenance of the equipment, the user must have the following tools:

- A clean work bench.
- A kit of cleaning (baby wipes, absolute ethanol, lint-free, clean cloth).

#### Preventive maintenance frequency

The preventive maintenance actions are limited to the cleaning of the equipment. The preventive maintenance will have to be carried out as indicated in the following table:

Item	Frequency
Rear air fan grids	monthly.
External parts	monthly.
Internal glasses	monthly.
Translucent frame	weekly, minimum.
Glass bottom drawer	weekly, minimum.

### FAN AIR GRIDS CLEANING



Figure 116
Fan cleaning.

Block the fan propellers with a screwdriver and blow with a compressed air small bottle (office equipment furniture).

Never obstruct the air grids.

Recommended frequency: once per month.

#### **EXTERNAL PARTS CLEANING**



Figure117
Surface cleaning.

Cover, laterals and front sides, except transparent parts

Use a non-greasy, non-abrasive cleaner or warm water. Dry with a lint-free, clean cloth.



Figure 118 LCD cleaning.

## LCD display and transparent parts of the front side

Use a non-greasy, non-abrasive cleaner or warm water. Dry with a lint-free, clean cloth. Take care not to let run cleaning liquid into the lower part of the LCD display.

#### INTERNAL PARTS CLEANING



Figure 119
Translucent tray cleaning.

# Open the drawer. Remove the plastic frame. Use a non-greasy population.

Translucent plastic frame

3. Use a non-greasy, non-abrasive cleaner or warm water to clean the translucent tray. Dry with a lint-free, clean cloth.



Figure 120 Glass bottom cleaning.

#### Drawer glass

- 1. Open the drawer.
- Use a non-greasy, non-abrasive cleaner or warm water to clean the drawer glass. Dry with a lint-free, clean cloth.
- 3. Place the translucent frame in its notch and close the drawer.

#### INTERNAL GLASS CLEANING

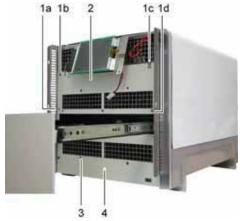


Figure 121 Removing the front plates.

#### Proceed as follows:

- 1. Remove the front panel (refer to the *Maintenance manual*).
- 2. Open the drawer.
- 3. Remove the 4 screws (1a to 1d) and remove the upper front plate (2).
- 3. Remove all the screws (3) and remove the lower front plate (4).

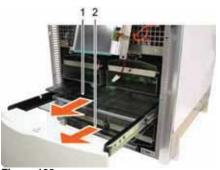


Figure 122
Removing the upper and lower glasses.

- 4. Remove the upper (marker 1) and lower (marker 2) glasses and clean them.
- 5. Remount in reverse way.

#### REPORT PRINTER

Refer to the manufacturer manual as far as regular maintenance and troubleshooting are concerned.

#### BARCODE READER

Regularly check the cleanness of the emitting glass. Wipe the surface with a lint-free, clean cloth.

Refer to the manufacturer manual as far as troubleshooting is concerned.

**ERROR MESSAGES** 

# ERRORS AND CURATIVE MAINTENANCE PROCEDURES

This chapter describes the main error and their solution, if exists.

#### REMINDER

- The MacoTronic B2 automatically prints validation labels and report which indicates if the illumination cycle is correct or not.
- Only plasma bags with MB treated plasma mention can be considered as correctly treated according to the THERAFLEX MB-Plasma process.
- The plasma bags with *Invalidated treatment* have to be thrown away. This means that the cycle has been interrupted or a failure occurs during the cycle.

#### POWER SUPPLY FAILURE

- In case of power failure and when no UPS (Uninterruptible Power Supply) is installed, you will find the machine in a switch off status. To restart, you need to push the switch on button after having removed the plasma bags remained inside the illumination chamber (if not, the LED autotest could failed).
- If power failure occurs during running cycle, the bags have to be discarded (no label and report will be printed or printable for those bags). If power failure occurs after the end of the cycle, but before the label has been printed, then it will be possible to reprint this label using the reprint function as described in chapter

Reprint report or label, on page 72.

 A warning message is display during autotest in case of power failure, please refer to autotest error section for more details.

#### HOW TO UNDERSTAND AND HANDLE ERRORS MESSAGE

- The *MacoTronic B2* is performing testing at various stages of its use to provide a safe treatment.
- When the *MacoTronic B2* detects an problem or an unusual behavior, a error code or an error screen will be display to warn the user.
- An error message doesn't always mean that the machine is defective or that the treatment is not correct and that the bag has to be thrown away. Some messages are only warning messages.

- Tests are performed during:
  - The initialization of the machine: Autotest
  - The bag identification: Bag Data Validation
  - Before starting a cycle: Pre Tests
  - During the cycle: Cycle Tests
- The only errors which are critical and could lead to the bag destruction are the errors which happens during the cycle
- When a problem occurs always write down the date and time, the error code and what you were doing on the machine just before the errors have occurred. Then call your *MacoPharma* representative.

#### **AUTOTEST ERRORS**

An Autotest error occurs during machine startup.

All the Autotest error code will be in the following range: 1000~1999

If an error occurs the only verification that you can do is to check if there is nothing forgotten in the drawer and restart the machine, if the problems persist contact a MACOPHARMA representative

#### Initialization



Figure123
Screen displayed if an initialization error occurs

#### **Error level**

Critical error.

#### Cause

Software configuration is not correct

#### Consequence

Autotest cannot be started.

#### **Corrective action**

Close the drawer.

#### **Drawer closing**



Figure124
Screen displayed when drawer is opened

#### **Error level**

Warning error.

#### Cause

The drawer is not close

#### Consequence

Autotest cannot be started.

#### Corrective action

Close the drawer

#### Restart after power failure

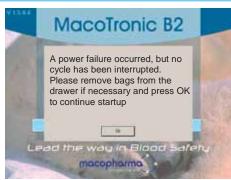


Figure 125
Restart after power failure with a cycle running

#### **Error level**

Warning error.

#### Cause

A power failure occurred but no cycle was running

#### Consequence

The machine has not been switched off properly

#### Corrective action

Open the drawer to check there are bags remaining in the machine.

If there are bags you will be able to print label and report from the reprint menu

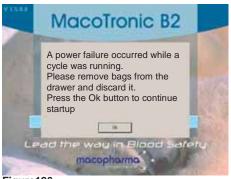


Figure126

Restart after power failure with a cycle running

#### Error level

Warning error.

#### Cause

A power failure occurred and a cycle was running

#### Consequence

The cycle has been abort, the treatment is not correct and the bags have to be discard.

#### Corrective action

Open the drawer to remove and bags and destroy it

#### Autotest errors

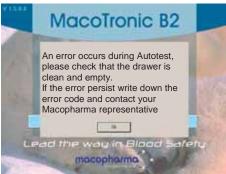


Figure 127
Autotest error message.

#### Error level

Critical error.

#### Cause

A hardware problem has been detected

#### Consequence

The machine cannot be use



Figure128
Autotest error message.

#### **Corrective action**

Open the drawer to check if there is nothing remaining in the machine.

Press the restart button.

If the problem persists write down date, time and error code. Then contact your *Macopharma* representative

#### BAG DATA VALIDATION ERRORS

Bag data validation error occurs just after the bag identification step.

An error is triggered if the bag identification data are incorrect or incoherent.

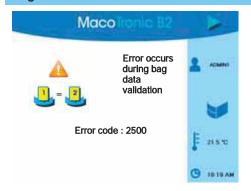
Bag data can be checked by the system itself, by the Macotrace or by the RFID reader.

Depending which system trigger the error a different screen will be displayed, the error code will help you to understand how to fix the problem

All the bag data validation error code will be in the following range: 2000~2999

If an error occurred, the bag identification screen will be displayed again after error acknowledgement, make sure that the data entered are correct.

#### Bag data validation errors



#### **Error level**

Warning error.

#### Cause

Bag 1 identification data equals bag 2 identification data

#### Consequence

Cycle cannot be started.

#### Corrective action

Restart bag identification step

Figure 129
Bag data validation error



Figure 130 RFID bag data validation error

#### **Error level**

Warning error.

#### Cause

Bag identification data contained in the RFID tags are not correct

#### Consequence

Cycle cannot be started.

#### **Corrective action**

Find in the error code table the signification of the error and check the content of RFID tags

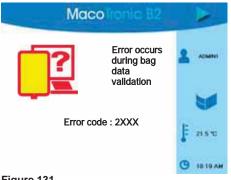


Figure 131 RFID bag data validation error

#### Error level

Warning error.

#### Cause

Bag identification data are refused by the *Macotrace* 

#### Consequence

Cycle cannot be started.

#### Corrective action

Find in the error code table the signification of the error and check the *Macotrace* 

#### **History Errors**



Figure 132
Bag already illuminated.

#### **Error level**

Warning error.

#### Cause

The bag has already been illuminated on this equipment.

#### Consequence

The *MacoTronic B2* warns the user who can choose continuing or canceling the cycle.

#### **Corrective action**

Click:

- Yes to continue.
- No to return to the identification screen.
   Remove the bags and contact the administrator.

#### RFID error code table

Test Name	Error Code	Description	Actions
Reader Status	2010	Reader 1 is defective	Restart the machine, if the problems persist contact your <i>MacoPharma</i> representative
Reader Status	2020	Reader 2 is defective	
Tag Detection	2100	No tag have been detected on bag 1 and 2	Check if the bags are properly place in the drawer and if the tags are valid
Masks	2211	Wrong Donation Number for Bag 1	
Masks	2212	Wrong Product code for Bag 1	
Masks	2213	Wrong Lot Number for Bag 1	Checks the bag
Masks	2221	Wrong Donation Number for Bag 2	identification data format
Masks	2222	Wrong Product code for Bag 2	
Masks	2223	Wrong Lot Number for Bag 2	
Kit Type	2310	Wrong Kit Type for Bag 1	Use a correct Theraflex kit
Application Code	2320	Wrong Kit Type for Bag 2	and contact your MacoPharma representative
Bag Status	2410	Bag 1 has already been illuminated	
Bag Status	2420	Bag 2 has already been illuminated	

#### Datamanager error code table

Test Name	Error Code	Description	Actions
DM	2611	Bag 1 is reserved on DM by another machine	
DM	2612	Bag 1 has already been illuminated according to the DM	
DM	2613	Bag 1 is refused by the DM for unknown reason	
			Check the bag identification data and the <i>Macotrace</i> list
DM	2621	Bag 2 is reserved on DM by another machine	
DM	2622	Bag 2 has already been illuminated according to the DM	
DM	2623	Bag 2 is refused by the DM for unknown reason	

#### PRETEST ERRORS

Pretest error occurs just before starting the cycle.

This means that if an error occurs during pretest the cycle hasn't started yet therefore you can try to run another cycle with these bags

All the bag data validation error code will be in the following range: 3000~3999

#### **Drawer Closing**



Figure 133 Screen displayed when drawer is opened.

#### **Error level**

Warning error.

#### Cause

Drawer opened.

#### Consequence

Illumination cannot be started.

#### Corrective action

Close the drawer.

#### **Pretest Errors**



Figure134 Machine too hot



Figure135 Hard drive full

#### **Error level**

Warning error.

#### Cause

Machine temperature is higher than the threshold set in the temperature settings menu

#### Consequence

Cycle cannot be started.

#### Corrective action

Adjust the threshold or wait that the machine cool down. If the problem persist contact you Macopharma representative, some fan might be defectives.

#### **Error level**

Warning error.

#### Cause

The hard drive is full

#### Consequence

Illumination data cannot be store, therefore the cycle won't start.

#### Corrective action

Backup the file through the USB menu and restart the cycle.

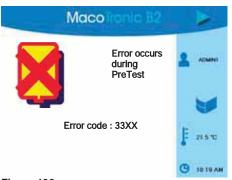


Figure 136
Error during check bag presence test

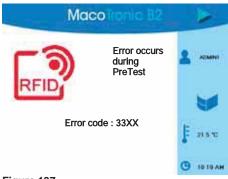


Figure 137
Error during check bag presence test

# Error occurs during PreTest Error code : 3XXX

Figure 138 Hardware error

#### **Error level**

Warning error.

#### Cause

Error during check bag presence test.

#### Consequence

Cycle cannot be started.

#### **Corrective action**

Find in the error code table the signification of the error and the bag declaration

#### **Error level**

Warning error.

#### Cause

Cannot write illumination data on the tag

#### Consequence

Cycle cannot be started.

#### **Corrective action**

3610 Bag one / 3620 Bag two Disable RFID functionality or replace the RFID tag

#### **Error level**

Warning error.

#### Cause

Hardware problem

#### Consequence

Cycle cannot be started.

#### **Corrective action**

Contact you Macopharma representative

#### Error code table

Error Code	Description	Actions
2611	Bag 1 is declared but not detected	
2612	Bag 2 is declared but not detected	B
		Restart the bag identification step
2621	Bag 1 is detected but not declared	Stop
2622	Bag 2 is detected but not declared	

#### CYCLE ERRORS

Cycle error occurs during the cycle and leads to an invalid treatment.

Bags with an invalid treatment have to be discarded

All the cycle error code will be in the following range: 4000~4999

#### Manual cancellation

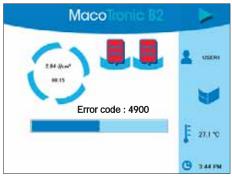


Figure139

Screen displayed after click on the stop button during an illumination cycle.

#### **Error level**

Critical error.

#### Cause

The cycle has been stopped by the user

#### Consequence

Illumination is stopped.

The failed source appears in red color on the screen.

A data back-up with error code (invalid treatment for every bag) is carried out.

#### **Corrective action**

Non applicable

#### **Autotest Error**

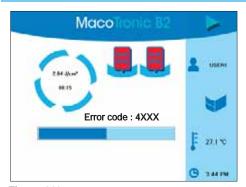


Figure 140 Cycle error

#### **Error level**

Critical error.

#### Cause

An hardware error occured

#### Consequence

Illumination is stopped.

The failed source appears in red color on the screen.

A data back-up with error code (invalid treatment for every bag) is carried out.

#### Corrective action

Write down the error code and discard the bags

#### CYCLE WARNINGS

Cycle warnings are displayed at the end of the cycle.

These warning mean that something went wrong during the cycle, but the treatment is still valid.

An icon will be display under the bag for which the errors occurs.

Please note that multiple icon can be display

#### Bag temperature warning



Figure 141
Bag Temperature warning

#### **Error level**

Warning error.

#### Cause

Bags temperature have exceeded the threshold set in the temperature settings menu

#### Consequence

Inactivation result is not affected Depends of your operating mode

#### **Corrective action**

Change the thresholds

Check the plasma temperature before inactivation

If the problem persist contact you *Macopharma* representative, some fans might be defective

#### **RFID** warning



Figure 142 RFID warning

#### Error level

Warning error.

#### Cause

RFID tag cannot be written

#### Consequence

Illumination data cannot be written on the tags

#### **Corrective action**

Replace the tags

#### DM warning

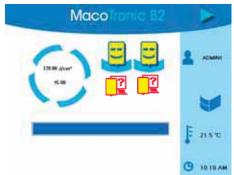


Figure 143 RFID warning

#### Error level

Warning error.

#### Cause

Connection error with the DataManager

#### Consequence

Illumination data can be transferred to the *Macotrace* 

#### **Corrective action**

Check if the **Datamanager** is switched on and correctly connected to the machine.

Perform a manual import on the *Macotrace* once the problem is fixed.

#### Maintenance warning

Figure 144



#### Error level

Warning error.

#### Cause

Maintenance has to be done for optical block

#### Consequence

Illumination time may be longer

#### **Corrective action**

Contact your *Macopharma* representative to plan the maintenance

#### **ERROR CODE ON ILLUMINATION REPORT**

All errors and messages are logged in the report journal.

The report journal is automatically printed after each illumination cycle on the report printer.

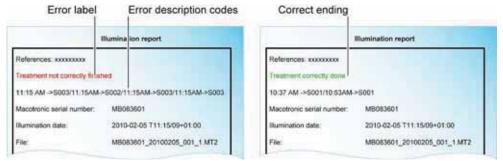


Figure 145
Example of illumination report with error codes (left side, or without report code (right side).

TECHNICAL DATA

## TECHNICAL DATA

#### **A**PPROVALS

Electrical EN 61010-1:2010 (Security rules for electrical apparatus for measuring,

safety regulation and the laboratory).

EMC EN 61326-1:2006 (Measuring, Control and Laboratory Electrical

systems). Class A equipment.

#### **GENERAL DATA**

**Purpose** 

Illumination of plasma bags according the THERAFLEX MB-

Plasma procedure.

**Displayed information** 

uman machine interface: 5.7" LCD touch color screen (640 x 480 pixels).

Other displayed data: bag ID, light intensity, energy delivered, temperature, graph

and progress bar.

Capacity

Number of bags: illumination of 2 bags per cycle.

Type of bag: illumination bags according the THERAFLEX MB-Plasma

procedure.

Other

Cycle time: Around 15 minutes.

#### CONSTRUCTION DATA

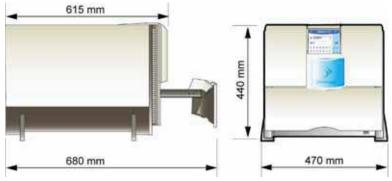
#### **Mechanical data**

Casing material: painted stainless steel.

Panel material: painted polyurethane.

Mass: 54 kg.

Dimensions: 470 (W) x 680 (d) x 440 (H) mm.



**Electrical power supply** 

Power supply voltage: 110-240 VAC. Automatic selection.

Max. voltage fluctuation:  $\pm$  10 %. Frequency:  $\pm$  50/60 Hz.

Protection: 2 x fuses FST Ø 5 x20 mm, 10 A (F10AL250V).

Absorbed energy: 750 W

**Noise level** 

Noise level 57 dBa

**Electrical connections** 

Mains power: IEC connector (2 phases + earth).

Ethernet: for report printer (if used)

USB: 2 rear connectors and 2 front connectors.

Barcode Printer: through one specific USB connector.

Barcode reader: through one specific USB connector.

Optical modules (optical blocks)

Power supply: 24 V DC.

Number of LED per 24

module:

Type of LED: LED Luxeon Emitted wavelength:  $627 \text{ nm} \pm 10 \text{ nm}$ . Light power: 3W (per LED).

Power light control: PWM control via optical block board.

Light intensity control: 1 measurement photodiode per optical block.

Number of optical modules: Aluminum radiator and one fan per optical module.

Delivered energy: as per THERAFLEX MB-Plasma procedure (120 J/cm²).

Safety: detection of out of order illumination LEDs.

Illumination parameters: protected by password. Setting from the LCD display

commands.

Others functions

Temp management: 2 pyrometers (one per bag).

Measurement range: 0 to 40 °C. RFID reader: optional

#### **ENVIRONMENTAL DATA**

**Working conditions** 

Temperature: use in an air-conditioned room between +20°C +/- 2°C

Altitude : ≤ 2000 meters.

Pollution level :  $\leq$ 2 (according EN 61010-1). Humidity :  $\leq$ 80% (non-condensed).

**Transport conditions** 

Temperature: -30 °C to +75 °C.

Humidity: 10 to 80 % (non-condensed).

Atmospheric pressure: 500 hPa to 1060 hPa.

Storage conditions

Temperature: +10 °C to +40 °C.

Humidity: 10 to 80 % (non-condensed).

Atmospheric pressure: 500 hPa to 1060 hPa.

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# Appendix A

#### Revision changes for Macotronic B2 user Manual

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